EXHIBIT D

IN THE COURT OF COMMON PLEAS
PHILADELPHIA COUNTY
TRIAL DIVISION

IN RE: PELVIC MESH LITIGATION — MAY TERM 2013
No. 3913

PATRICIA L. HAMMONS,

Plaintiff,

vs.

ETHICON, INC., et al.,

Defendants,

- - -

SEPTEMBER 26, 2015

- - -

Deposition of RALPH ZIPPER, MD, held at Zipper Urogynecology Associates, 200 South Harbor City Boulevard, Suite 401, Melbourne, Florida, commencing at 9:52 a.m., on the above date, before Joan L. Pitt, Registered Merit Reporter, Certified Realtime Reporter, and Florida Professional Reporter.

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GOLKOW TECHNOLOGIES, INC.
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deps@golkow.com

Q. And are those primarily polypropylene midurethral slings?

A. They are almost exclusively retropubic polypropylene slings. I have not placed any material through the transobturator foramen in quite some time.

Q. And what type of -- what brand of midurethral sling do you currently use?

A. The most common one is the AMS SPARC sling.

Q. AMS what?

A. SPARC, S-P-A-R-C.

Q. And I assume that you've done thousands of SUI procedures using midurethral slings; is that true?

MR. THORNBURGH: Objection. Over what time period?

MR. MORIARTY: In his career.

A. Yes.

Q. So this paragraph on the beginning of page 3 of your report says, "I have worked closely with engineers to develop devices, including slings."

Was that with the medical device manufacturers, Bard, or AMS, or another?

A. I actually worked with an engineer employed by myself to improve and develop sling and pelvic organ prolapse technology in a deal with Mpathy to take their

low efficacy mini sling and sheet mesh to the US market in a diversified product line with improved efficacy, create sales, and get an exit.

I spent approximately one and a half years of my life and thousands of hours working on the engineering and deployment of those product lines, and those modifications were commercialized and subsequently sold to Coloplast, and the details of those interactions, which involve thousands of pages, may be or may not be confidential following the settlement that took place.

Q. That's what that lawsuit was about, basically; right?

A. Yes.

Q. In Mrs. Hammons -- we can talk more about this later.

What is the basis for your opinion that she suffered some clinical signs and symptoms secondary to contraction of mesh?

A. Signs and symptoms of contraction. Signs of contraction include failure of the device to perform according to its implication, which is long-acting, long-term stabilization of pelvic supporting structures. I believe it's -- the wording is quite similar in the

atypical familiarity with the mesh manufacturing process and the physical properties of mesh.

However, I do not represent myself as an expert in materials science.

Q. Okay. The work that you just described, is that something different than -- let me withdraw that.

When I asked you the initial question about do you have training beyond what a doctor or urogynecologist has, you said something about "from my experience or my research," and then I just -- and then you just explained to me some experience that you've had. Okay?

Is the research that you've done separate from what you've just explained to us about your work with that company?

A. Yes, it's in addition to that. I would sit down with manufacturers, I would get to talk to engineers and hear things about the manufacturing process and mesh properties that a urogynecologist or gynecologist would not hear, and then I would go home and dig deeper and do my own research.

That's why many of these articles on the reliance list I was familiar with long before I was involved in this litigation.

But I did not obtain an engineering degree in materials science or attend classes in materials science when in training.

Q. Okay. When was this work that you're describing in the development of those products?

A. I can't recall. Probably starting in or about 2006 going through probably about 2009 or 2010. This is just a guess.

THE WITNESS: Dinner break?

MR. THORNBURGH: I've got some food in my duffle bag.

THE WITNESS: Will you share?

(Discussion off the record.)

THE WITNESS: Mr. Moriarty, while you're doing your review, I think I'll hit the head, if that's okay.

MR. MORIARTY: Go ahead.

(Recess from 4:45 p.m. until 4:52 p.m.)

(Zipper Exhibit No. 16 was marked for identification.)

BY MR. MORIARTY:

Q. Doctor, I'm going to hand you what I've marked as Exhibit 16. It's an article that's on your reliance list and you refer to it at page 19 of your report in

A. I only know that I opined. That's it.

Q. Okay. Do you hold yourself out in any context outside litigation in being an expert in FDA regulations regarding labeling?

MR. THORNBURGH: Objection.

A. It's an interesting question without an easy answer. Most labeling experts sit on the side -- have experience on the side of the FDA, have worked in the FDA, often in the ODE or other departments in the FDA, and then go out into the private sector.

My experience is looking at it from the other end in product development and working through the regulations as an executive in the device company. And so where I do not hold myself out as a regulatory expert, I do hold myself out as having an expert level of knowledge on the corporate side of helping to determine regulatory pathways and pursue those regulatory pathways.

Q. Handing you Exhibit 6B.

MR. MORIARTY: Dan, I think I gave you the whole pack at one time. Let me know if I didn't.

Q. Is that a printout of a section of your website entitled "Dr. Zipper Explains Urgency Incontinence"?

A. It may be.

Q. How do you know you are?

A. It has become the industry standard for clients such as yours, Ethicon, to determine who the national thought leaders are, and device companies have qualified me as a national thought leader.

Q. Okay. Did you ever do any preceptor work for Ethicon?

A. I do not recall.

Q. Have you ever performed studies on contraction or shrinkage rates of mesh?

A. I have not.

Q. Have you ever performed a study on degradation of mesh?

A. I have not.

Q. Have you ever performed a study on the difference between laser or mechanically cut mesh?

A. I have not.

Q. Have you ever prepared a 510(k) application?

MR. THORNBURGH: Asked and answered.

A. I've assisted, but I have not been the sole preparer of a 510(k) application.

Q. Was that for one of the products intended to be manufactured and sold by one of your companies?

A. Yes.

C E R T I F I C A T E

I, JOAN L. PITT, Registered Merit Reporter, Certified Realtime Reporter, and Florida Professional Reporter, do hereby certify that, pursuant to notice, the deposition of RALPH ZIPPER, MD, was duly taken on SEPTEMBER 26, 2015 at 9:52 a.m., before me.

The said RALPH ZIPPER, MD, was duly sworn by me according to law to tell the truth, the whole truth, and nothing but the truth, and thereupon did testify as set forth in the above transcript of testimony. The testimony was taken down stenographically by me. I do further certify that the above deposition is full, complete, and a true record of all the testimony given by the said witness.

_____

JOAN L. PITT, RMR, CRR, FPR

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)